IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRIT OF TEXAS
DALLAS DIVISION

THE UNITED STATES OF AMERICA ex. rels., DAVID CHOATE AND DON PYBURN,

Plaintiffs,

vs.

DNA STAT, PRIMEX CLINICAL LABORATORIES, INC., RESEARCH and DEVELOPMENT INSTITUTE INCORPORATED, and MITCH EDLAND

Defendants.

CASE NO. _____

3-14CV-1691B

FILED *IN CAMERA* AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2).

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PLAINTIFFS' ORIGINAL COMPLAINT [FILED UNDER SEAL]

May 7, 2014

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PLAINTIFFS' ORIGINAL COMPLAINT [UNDER SEAL]

Relators David Choate and Don Pyburn ("Relators") file this original complaint under 31 U.S.C. § 3729, *et seq.* (the "False Claims Act"), to recover damages, penalties, and other remedies established by the False Claims Act on behalf of the United States.

I. INTRODUCTION

This is a case about a massive fraud against the Medicare program through an illegal kickback scheme used to induce Medicare providers to request pharmacogenomic[1] testing. On information and belief, DNA Stat owner and fraud mastermind Mitch Edland ("Edland") discovered a lucrative scheme to defraud Medicare while at a laboratory called Natural Molecular, a company that, on information and belief, the Center for Medicare and Medicaid Services investigated and ultimately removed from the Medicare program. But rather than learning from Natural Molecular's just fate, Edland reincarnated the scheme with a new spin, apparently believing he can escape liability by creating a web of so-called "independent" contractors.

Edland and his company DNA Stat have conspired, and continue to conspire, with Primex Clinical Laboratories and Research and Development Institute ("RDI") to implement his fraudulent scheme. In particular, the conspirators set up a so-called "clinical study" as a means to induce physicians to order Medicare-reimbursed pharmacogenomic testing in exchange for compensation, with the physicians believing they are being paid for providing study data rather than as a kickback. In actuality, the physicians receive kickbacks for up to $75 per patient. And

[1] Pharmacogenomics is the study of genetic variations that influence individual response to drugs. AMA website, "Pharmacogenomics," available at http://www.ama-assn.org/ama/pub/physician-resources/medical-science/genetics-molecular-medicine/current-topics/pharmacogenomics.page.

as a result of the kickback scheme, physicians order tests believing they are participating in a clinical study, when in fact they are participating in a scheme to defraud Medicare. The study is not intended to advance scientific knowledge but merely as a cover and vehicle for the kickbacks.

As a DNA Stat trainer admits in a recorded training session, the purpose of the so-called "clinical study" is to drive test volume:

> If [physicians] want to continue [in the study] they can and then the account representative will still get a revenue? Absolutely. We hope they do continue. We all get paid. Yup, you bet. You bet. We're looking for volume. It is about getting tests in the door.

Taking another page from the Natural Molecular playbook, the conspirators also provide high-performing physicians with medical assistants to administer the tests—on the conspirators' dimes—both as a kickback to the physicians and so that the employees can drive test volume as the conspirators' "full time representation" in those physicians' offices.

This fraudulent scheme specifically targets Medicare dollars and patients. In particular, the conspirators know that unlike many private insurance payors, Medicare pays for 100% of the cost of pharmacogenomic test panels, so DNA Stat trains sales representatives to hone in on physicians with a high-percentage of Medicare patients. In fact, on information and belief, over 80% of DNA Stat revenue comes from tests reimbursed by Medicare. DNA Stat also requires physicians to order medically unnecessary tests by requiring the physicians to order every possible test panel as a condition for receiving the kickbacks—all so that the Defendants can receive higher reimbursements from Medicare. But far from a merely financial impact, the fraudulent plot also induces physicians to unnecessarily modify patient treatment plans. In particular, physicians only receive the full $75 kickback if they change a patient's medication as

a result of the pharmacogenomic testing, resulting in potentially dire consequences for often-vulnerable Medicare patients.

II. FILING UNDER SEAL

1. In accordance with 31 U.S.C. § 3730(b)(2), this complaint is filed *in camera* and under seal and will not be served on the Defendants until the Court so orders. Also in accordance with 31 U.S.C. § 3730(b)(2), a copy of this complaint and a confidential written disclosure of substantially all material evidence and information that Relators currently possess have been provided to the United States Attorney General's Office.

2. Plaintiffs' Disclosure Statement is supported by the material evidence known to Relators at this filing establishing the existence of Plaintiffs' False Claims Act claims. Because the statement is submitted to the Attorney General and to the United States in their capacity as potential co-counsel in the litigation, the Relators understand this disclosure to be confidential.

III. THE PARTIES

3. Plaintiff, David Choate, ("Choate" or "Relator") is a citizen of the United States and a resident of the State of Texas. From October 4, 2013 to December 13, 2013, Mr. Choate was an independent contractor that performed services on behalf of Defendant DNA Stat LLC ("DNA Stat").

4. Plaintiff, Don Pyburn, ("Pyburn" or "Relator") is a citizen of the United States and a resident of the State of Texas. From October 16, 2013 to December 1, 2013, Mr. Pyburn was an independent contractor that performed services on behalf of DNA Stat.

5. Mr. Choate and Mr. Pyburn are collectively referred to as "Relators" or "Plaintiffs." Relators bring this action based on their direct, independent, and personal

knowledge and also on information and belief. They bring this action against Defendants for violations of the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, for the United States and for themselves, pursuant to the authority granted by 31 U.S.C. § 3730(b).

6. Relators are an original source of the information underlying this Complaint and provided to the United States. They have direct and independent knowledge of the information on which the allegations are based. Relators are contemporaneously providing to the United Stated Attorney General a Confidential Disclosure Statement which presents substantially all material evidence and information Relators currently possess pursuant to 31 U.S.C. § 3730(b)(2).

7. Defendant DNA Stat LLC ("DNA Stat") is organized under the laws of Texas and has its principal place of business in the Northern District of Texas, at 4500 Westgrove, Suite 315, Addison, Texas 75001. DNA Stat markets pharmacogenomic tests and "manages" the provision of services related to the tests.

8. Defendant Primex Clinical Laboratories, Inc. ("Primex") is organized under the laws of California and, on information and belief, has its principal place of business at 16742 Van Nuys, California, 91406. Primex performs clinical laboratory services. On information and belief, Primex is enrolled in the Medicare program.

9. Defendant Research & Development Institute ("RDI") is organized under the laws of Nevada. On information and belief, RDI has its principal place of business at 16742 Van Nuys, California, 16760, at the same industrial complex as Primex. On information and belief, RDI is a contract research organization that performs services for Primex and DNA Stat.

10. Defendant Mitch Edland is the CEO, president, owner, and founder of DNA Stat. On information and belief, Edland currently resides in Frisco, Texas and works in Addison, Texas.

IV. JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345.

12. There have been no public disclosures of the allegations or transactions contained herein that bar jurisdiction under 31 U.S.C. § 3730(e).

13. This Court has personal jurisdiction over the Defendants because, among other things, Defendants transact business in this District and engaged in wrongdoing in this District. Defendant DNA Stat also has its principle place of business in this District. Defendant Edland also resides and works in the district.

14. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Defendants transact business within this District; Defendants DNA Stat and Mitch Edland can be found and reside in this District, and acts proscribed by 31 U.S.C. § 3729 occurred in this District.

V. APPLICABLE LAWS

A. The False Claims Act

15. False Claims Act ("FCA") liability attaches to any person who knowingly presents or causes a false or fraudulent claim to be presented for payment, or to a false record of statement made to get a false or fraudulent claim paid by the government. 31 U.S.C. § 3729(a)(1), (2).

16. Under the False Claims Act, the terms "knowing" and "knowingly"

(A) mean that a person, with respect to information—

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) requires no proof of specific intent to defraud. 31 U.S.C. § 3729(b).

17. The term "claim": means any request or demand, whether under a contract or otherwise, for money or property … that

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United State Government—

(iii) provides or has provided any portion of the money or property requested ore demanded; or

(iv) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

18. The False Claims Act is violated not only by a person who makes a false statement or a false record to get the government to pay a claim, but also by one who engages in a course of conduct that *causes* the government to pay a false or fraudulent claim for money. In response to the Supreme Court's decision in *Allison Engine v. U.S. ex rel. Sanders*, 553 U.S. 662 (2008), Congress clarified that liability under the FCA "attaches whenever a person knowingly makes a false claim to obtain money or property, any part of which is provided by the Government without regard to whether the wrongdoer deals directly with the Federal

Government; with an agent acting on the Government's behalf; or with a third party contractor, grantee, or other recipient of such money or property." S. Rep. No. 111-10 at 11.4.

B. The Anti-kickback Statute and the Stark Law

19. The federal Anti-kickback Statute prohibits (1) the solicitation or receipt of remuneration in return for referrals of Medicare patients, and (2) the offer or payment of remuneration to induce such referrals. 42 U.S.C. § 1320a-7b(b).

20. The Stark Law prohibits physicians from referring Medicare patients to an entity for certain "designated health services" including … if the referring physician has a nonexempt "financial relationship" with such entity. 42 U.S.C. § 1395nn(a)(1), (h)(6). Stark defines a financial relationship to include a "compensation arrangement" in which "remuneration" is paid by a provider to a referring physician "directly, indirectly, overtly or covertly in cash or in kind." § 1395nn(a)(2), h(1).

21. Both the Anti-kickback Statute and the Stark law include a safe harbor for "personal services and management" arrangements, but they do not apply if the payments are volume-based. 42 CFR § 1001.952(d); 42 U.S.C. § 1395nn(2).

22. Courts across jurisdictions, including in the Fifth Circuit, have agreed that schemes in violation of the Anti-kickback Statute and Stark Law to induce payment from the United States create liability under the FCA. *See, e.g., United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997) (overturning the district court's dismissal of FCA causes of action based on the submission of claims for payment prohibited by the Stark Law and the submission of claims with false certifications of compliance with the Anti-kickback and the self-referral laws).

C. Medical Necessity

23. Medicare cannot reimburse for expenses that are not medically necessary. Social Security Act, § 1862(a)(1).

24. It is among the first principles of health care that treating physicians must decide what tests or services are medically necessary for the diagnosis and treatment of their patients. Through the 1990s, in a series of civil and criminal enforcement actions that became known as "Labscam," the federal government pursued cases against a number of clinical laboratories that undermined the essential tenet of the health care system by, among other things, creating test panels that deceived physicians into ordering more lab tests than were reasonable and necessary, and by submitting claims for this excessive testing to federal health care programs, including Medicare and Medicaid.

25. In response to these cases, in 1998 the OIG issued guidance advising clinical laboratories that they "should take all reasonable steps to ensure that [they are] not submitting claims for services that are not covered, reasonable and necessary." *See* Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45076, 45079 (Aug. 24, 1998). Among the specific measures the OIG suggested is that laboratories should construct their test ordering forms to "promote the conscious ordering of tests by physicians" and to ensure that physicians make "an independent medical necessity decision with regard to each test the laboratory will bill." *Id.*

VI. DEFENDANTS' FRAUDULENT SCHEME TO INDUCE PHYSICIANS TO REQUEST PHARMACOGENOMICS TESTS THROUGH UNLAWFUL KICKBACKS

A. Pharmacogenomic Testing Provides a Promising New Tool and an Area Ripe for Fraud

26. Pharmacogenomics is a relatively new but exploding area of research that studies how genetic variations influence an individual's response to drugs. Pharmacogenomics uses a saliva-based testing method (called "buccal swabs") to detect genetic enzymes associated with the metabolism of medications, thereby measuring whether an individual properly metabolizes certain drugs.

27. A drug that that is not properly metabolized can build up in the body and cause potentially serious "adverse reactions." On information and belief, with over 2 million serious adverse reactions in the United States every year resulting in over 100,000 deaths, choosing the right medication at the right dosage is a major concern for physicians and patients.

28. Although a relatively new area, pharmacogenomics holds great promise for limiting adverse reactions and improved patient outcomes. According to the FDA, "[p]harmacogenomics can play an important role in identifying responders and non-responders to medications, avoiding adverse events, and optimizing drug dose."[2]

29. Preying on this hope for a revolutionary new tool to improve patient outcomes, DNA Stat instructs its marketers to trumpet this mantra—"Right Dose. Right Drug. Right Patient. Right Time."

30. In addition to the promise of better patient outcomes, physicians often find the new tool particularly attractive in an increasing era of "defensive-medicine." Concern over

[2] FDA, Table of Pharmacogenomic Biomarkers in Drug Labeling, available at http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm.

widespread lawsuits makes physicians highly motivated to find means to reduce liability. On information and belief, Defendants market these tests as an antidote to these lawsuits.

31. Although potentially revolutionary, most physicians know very little about pharmacogenomics testing. On information and belief, less than 1% of physicians currently use pharmacogenomics testing. Thus, when presented with a foreign and unorthodox marketing mechanism for these tests, most physicians have no previous experience with which to compare this new paradigm.

32. The final ingredient in a concoction for fraud is decreased physician profits, particularly for physicians with a large number of Medicare patients. For example, on information and belief, in recent years physician operating costs have increased several times faster than Medicare reimbursement rates. Decreasing physician margins combined with a lack of experience surrounding a new and promising test creates a landscape ripe for a massive fraud on Medicare.

B. Edland Implements the Fraud He Learned at Natural Molecular By Creating DNA Stat and Partnering with Primex and RDI

33. On information and belief, Edland has been involved in numerous multi-level and other direct marketing companies. Public records indicate Edland has started at least 12 companies in recent years related to the direct marketing of various products like dietary supplements and medical devices.

34. On information and belief, one of his recent multi-level ventures involved a company called Maxinternational that sells dietary supplements. While at Maxinternational Edland apparently became acquainted with an osteopathic doctor—Dr. Dale Bradley—that the

company hired to lend medical credence to its supplements. According to DNA Stat's website, the very same Dr. Bradley is now the so-called "medical director" for DNA Stat.

35. On information and belief, Mr. Edland discovered a new plot that could yield huge dividends by targeting Medicare dollars while working for a company called Natural Molecular. Natural Molecular is a laboratory that performs pharmacogenomic testing.

36. According to allegations in a case exposing Natural Molecular's fraud, which was filed by Millennium Laboratories against its competitor Ameritox, Ameritox and Millennium both compete in the market of pharmacogenomic testing. Ameritox used Natural Molecular as its "reference laboratory" for pharmacogenomic testing. Millennium alleges that both Ameritox and Natural Molecular provide kickbacks to physicians to induce ordering pharmacogenomic tests.

37. Of particular importance for the present case is the description of the following scheme whereby Natural Molecular allegedly created a "sham" clinical study as a front for providing kickbacks to physicians in exchange for tests:

> Natural Molecular allegedly offers physicians $95 per patient for enrolling patients in a "registry study" called the "PRIDE Registry," that is, upon information and belief, a sham designed to provide payments to physicians in exchange for referrals. Natural Molecular requires physicians to use its pharmacogenetic testing services for 30 days and 100 patients before they are eligible to begin enrolling patients and receiving payments. Natural Molecular informs physicians that after meeting this referral threshold, there is no limit to the number of patients they can enroll and that the registry is expected to be open for four years. National Molecular sales representatives have also informed physicians that these payments are intended to replace the loss of Medicare reimbursement for performing an oral swab for pharmacogenetic testing and that the process "takes about 20 seconds to complete." In addition, Natural Molecular enters into "Laboratory Service Agreements" with physicians pursuant to which it

pays physicians $15 per referred test for specimen collection and processing services.[3]

38. On information and belief, in addition to kickbacks in the form of paying physicians to sign-up patients for a sham study, Ameritox previously paid the government millions of dollars to resolve kickback claims involving providing "free collector personnel" to physician clientele to induce the referral of Medicare business. According to the complaint, the Center for Medicare and Medicaid Services excluded Natural Molecular from the Medicare program as a result of its investigation.

C. Edland Implements the Fraud He Learned at Natural Molecular By Creating DNA Stat and Partnering with Primex and RDI

39. On information and belief, while in management at Natural Molecular, Edland experienced first-hand a marketing plot that promised profits wildly exceeding anything he had obtained in his previous ventures. But rather than learning from the government investigation and demise of Natural Molecular, Edland set out to create a new and improved structure that could implement a similar scheme to line his pockets at the expense of the Medicare program.

40. The fraud required three primary components: (1) a "management company" to create a network of sales representatives that could induce physicians to order the tests by providing kickbacks; (2) a laboratory to perform the tests; (3) and a "research organization" to conduct the sham study used as a cover for the kickbacks.

41. For the management company, Edland created a new entity—Defendant DNA Stat LLC ("DNA Stat"). Incorporated in Texas in April 2013, DNA Stat is headquartered in Addison, Texas. DNA Stat's training webinar describes the company as the "management

[3] *Ameritox v. Millennium complaint*, attached hereto as Ex. 1.

company that manages services for all the moving parts for the labs," including managing the marketing and distribution of pharmacogenomics, managing the technology, managing the client services (*e.g.*, when practices "qualify" DNA Stat will supply technicians), and managing the team of pharmacists that provide the lab reports for physicians.

42. On information and belief, in an attempt to create the appearance of distance between his company and the kickbacks, and drawing on Edland's experience in multi-level marketing schemes, DNA Stat employs multiple levels of intermediate so-called "independent contractors" to implement its kickback scheme. The first level of "independent contractors" have exclusive marketing contracts with DNA Stat and are tasked with signing up the second level of intermediaries, who in turn hire the third level of actors, the sales representatives that actually directly sign up physician-customers.

43. DNA Stat expects the sales representatives to generate business primarily from their personal relationships. DNA Stat trains all three levels of "independent contractors" and provides complete direction and control over the contractors, despite self-serving language in their contracts giving the appearance of independence.

44. From DNA Stat's marketing materials, a physician could easily get the impression that DNA Stat is a laboratory rather than purely a marketing operation. But, on information and belief, DNA Stat does not have the ability to perform clinical tests and be reimbursed by Medicare (in fact its employees have no medical training, credentials, or licensures, other than perhaps the so-called "medical director" Edland borrowed from a previous direct marketing venture). Thus, it needed to partner with a laboratory to perform the actual tests and be reimbursed by Medicare.

45. In comes Defendant Primex Laboratories, Inc. ("Primex"). On information and belief, Primex was founded in 1996 and is located in Van Nuys, California. Primex purports to conduct numerous ostensibly legitimate laboratory services, including tests unrelated to pharmacogenomics. According to DNA Stat's training webinar, Primex is "approved by Medicare" and the tests are paid for by Medicare.

46. On information and belief, as an Independent Diagnostic Testing Facility ("IDTF") enrolled to provide services reimbursed by Medicare, Defendant Primex is required to fill out a certificate of compliance with the Anti-kickback Statute and the Stark Law.

47. As the final necessary conspirator, Primex and DNA Stat partnered with Defendant Research & Development Institute ("RDI") to implement the sham study. On information and belief, RDI is a Nevada Corporation founded in 2012, which is co-located in the same industrial complex as Primex in Van Nuys, California. On information and belief, RDI is shrouded in secrecy for DNA Stat employees, but was likely created for the sole purpose of purportedly conducting a clinical study. In its training documents for sales representatives, DNA Stat describes RDI as Primex's "Contract Research Organization." DNA Stat's training webinar similarly describes RDI as a "research group conducting a study on behalf of Primex."

48. Together, DNA Stat, Primex, and RDI implement the fraudulent kickback scheme. DNA Stat's training webinar refers to DNA Stat and Primex as "strategic partners", and all three entities actively participate in multiple aspects of the fraud. On information and belief, like the Natural Molecular scheme in conjunction with Ameritox, Edland's conspiracy involves kickbacks both in the form of sham study payments and free medical personnel, as described in

detail below. Additionally, the conspirators force physicians to request medically unnecessary tests by requiring that they order the full panoply of available tests to qualify for the kickbacks.

1. Primex, DNA Stat, and RDI Pay Physicians Monetary Kickbacks in Exchange for Test Requests

49. At its core, the kickback scheme is simple. DNA Stat's sales representatives induce physicians to order pharmacogenomic tests by offering up to $75 in kickbacks for every test ordered. Physicians receive $50 for each test ordered regardless of the test results. And if, and only, if the physician changes the patient's treatment after receiving the test results, the physician receives an additional $25. Thus, the scheme not only provides illegal kickbacks, but also financially incentivizes physicians to unnecessarily change patient treatments.

50. The sales representatives sell the physicians on receiving the kickbacks by pretending that the kickback is a payment for "participating in a clinical study" and "providing data for the study." In reality, and on information and belief, the study is a sham used solely as a cover for the kickback scheme. There is, in fact, no actual clinical study being conducted. The sham nature of the study demonstrates Defendants' fraudulent intent.[4] Further, *even if* the study were legitimate (which it is not), it would be illegal for DNA Stat to provide volume-based payments.[5]

a. A Detailed Description of the Study Kickback Scheme

51. DNA Stat documents describe in detail the procedure that the DNA Stat sales representatives follow to implement the sham study scheme involving DNA Stat, Primex, and

[4] Physicians can order tests without participating in the study, but a different lab other than Primex, called MDL, conducts these tests. MDL processes tests that are not part of the so-called clinical study, but according to DNA Stat training records MDL can process only 2-3,000 tests per month, significantly less than Primex. On information and belief, these tests constitute only a small portion of tests ordered, and DNA Stat marketing efforts focus almost entirely on selling tests using the study scheme.

[5] 42 U.S.C. § 1395nn(2).

RDI. First, the new physician or clinic must complete a Primex "Client Profile Form" to register the physician or clinic as "Clients for Primex and DNA Stat." The physician or clinic must also fill out a "Consulting Agreement for RDI," which sets forth RDI's contractual obligation for the $50 initial payment and the $25 contingent payment, which the physician only receives if she changes a patient's medication. DNA Stat collects all the forms and forwards them to Primex.

52. This kickback for study participation is a primary marketing message that DNA Stat sales representatives use to induce physicians to initially enter into a relationship with DNA Stat, Primex, and RDI.

53. After the physician's registration in the sham clinical study program is complete, RDI provides the physician with additional required forms that must be filled out for requesting the tests for each patient: (1) the "Clinical Test Consent Form"; and (2) the "PGX Clinical Study CRF." DNA Stat also provides the collection kits to physicians—free of charge—for performing the buccal swabs.

54. The Clinical Test Consent Form attaches the information to be provided to patients and a signature block through which the patient consents to participate in the so-called "study." It states that the "research study will help develop a "companion" test to the test your physician is requesting." In reality, the clinical study protocol, which sets forth the objectives for the study, makes no mention of this companion test as an objective of the "study." On information and belief the statement referring to the "companion" test" is false.

55. The Clinical Test Consent Form also indicates which of the nine potential "panels" the physician is requesting for the patient. The DNA Stat sales representatives are

trained to instruct the physicians and clinics to select option 7051, which indicates they are requesting all nine panels, *regardless of whether characteristics about the individual patient or the patient's medications* would necessitate the need for that panel.

56. The first five panels correspond to "pathways," which represent different enyzmes through which drugs are metabolized. The last four panels correspond to "risk factors" related to thrombosis.[6] If a physician were properly considering medical necessity, the physician should determine which panel or panels would be appropriate for each individual patient based on the patient's current medications, medical history, and other patient-specific factors. But, as described further below (Part VI(C)(3)), DNA Stat sales representatives instruct the physicians to select all nine panels for *every* patient as a condition of receiving the kickback, which in turn results in higher reimbursements from Medicare and increased revenue for Defendants.

57. The second form that must be filled out for each requested test is the PGX Clinical Study CRF Form, which stands for "Case Review Form." Completion of the CRF form is ultimately what enables the physician requesting the testing to obtain his or her first kickback payment. The CRF Form has three sections. The first section provides an (unusually small) set of information about the patient that the physician's staff fills out at the time that the buccal swab is collected.

58. The CRF form stays in the physician's office in a notebook at this point in the process, but the physician's office sends the buccal swab test kit to DNA Stat. After receiving the buccal swab samples, DNA Stat sends the samples to Primex in batches. Primex runs the

[6] Thrombosis is a blood clot in a vein or blood vessel.

samples and sends the results to DNA Stat for "interpretation by Pharm-Ds."[7] DNA Stat then makes the test results available for physicians through the DNAStat web-based portal[8] set up for the physicians. On information and belief, Primex bills Medicare (or in some cases the private payor) for the tests.

59. When the test report comes into the DNA Stat physician portal, someone from the physician's office fills in section 2 of the CRF Form based on the report, which indicates the results for each of the 9 panels. For each panel the test result will indicate the speed of the patient's metabolization as normal, poor, intermediate, rapid, or ultra-rapid.

60. Section 2 of the CRF Form also indicates the physician is supposed to provide recent lab work, but DNA Stat trains its representatives to inform physicians that this step is unnecessary. Thus, this portion of the form appears intended merely to give the appearance that the clinical study is more thorough and based on more data than it actually is. Finally, the physician indicates whether there were "any changes made due to patient's genotype"—meaning as a result of the test results. After the physician's staff completes sections 1 and 2, it faxes the CRF faxed to RDI. This final step constitutes the physician's request for the $50 payment, which the physician receives after completion.

61. Three months after faxing the CRF form, if the physician indicated in section 2 that a change was made to the medications, the physician can fax in section 3 to RDI for the second payment.

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[7] A Pharm-D is the professional doctorate obtained by most American pharmacists in recent years. DNA Stat's Pharm-Ds are also "independent contractors."

[8] The physicians and DNA Stat sales representatives both have access to the portal, which DNA Stat uses to track the tests requested and reports given to physicians. The interface is relatively simple. It allows selection of a physician or physician's office. Then it relates the physician or office with the patient names for each requested test, the date of the buccal swab, and whether the test has been completed.

62. On information and belief, the reason that the information is provided in two phases is to give the appearance to the physicians that the so-called study is actually measuring something—namely, the effect of the pharmacogenomic report on treatment decisions. Given that the physician is required to give two batches of information, Defendants provide the kickbacks in two installments, so as to maintain the appearance that the payments are connected to the provision of information for the sham study, rather than merely a kickback for ordering tests. Thus, the contingent $25 payment is tied to the physician performing the additional step of a three-month follow-up assessment, a step that is not required if the physician does not change the patient's medication. The net effect of the structure is to incentivize physicians to change treatments, so that they can receive the maximum possible payment.

b. The Secret Study Protocol and Other Evidence the Study Is a Sham

63. The evidence reveals that the Defendants know they are participating in a fraudulent scheme backed by a sham study and having at its core the primary goal of driving test volume. In a DNA Stat training tape, the trainer admits that "for compliance reasons" DNA Stat cannot directly pay the physicians for doing the tests. The trainer also admits that it would be "highly illegal" if the physician was paid for ordering the test rather than for participating in the study, and that it would be illegal if the payments came from DNA Stat or Primex rather than from RDI.

64. Thus, on information and belief, DNA Stat involves RDI in the study scheme in an attempt to escape illegality for inducing physicians to order tests through the study. But using

a contract research organization to implement the study in no way absolves Primex and DNA Stat of liability for the kickbacks filtered through the scheme.[9]

65. Additionally, DNA Stat Founder Edland himself admits in a conference call that the purpose of the study scheme is to drive test volume:

> The goal here is we want to get physicians paid.... We all see the benefits of that for multiple reasons. That will keep them encouraged and we will see them re-energized in what has slowed down when we get those [payments] in their hands.

66. In addition to the Defendants' own statements showing their intent to use the study to drive test volume, the clinical study protocol itself reveals that it is a sham. After much insistence, Relators obtained the sham clinical study protocol that Primex and DNA stat kept carefully concealed from its own sales representatives, as well as, on information and belief, from the participating physicians.

67. In general, a clinical study protocol is a "research plan" designed to outline the objectives and procedures for a clinical study and to safeguard the health of the participants.[10] A protocol contains information including the reason for conducting the study, the eligibility criteria, the number of participants, the length of the study, and the information that will be gathered.[11]

68. In the Primex study protocol here, numerous details of the protocol illustrate it was intended merely to give the appearance of legitimacy rather than to accomplish legitimate

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[9] A contract research organization ("CRO") is intended to provide support to a study sponsor in the form of research services outsourced on a contract basis. A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. 21 CFR § 312.52.

[10] U.S. National Institute of Health, ClinicalTrials.gov, available at http://clinicaltrials.gov/ct2/about-studies/learn.

[11] *Id.*

ends, particularly when juxtaposed with DNA Stat's instructions to sales representatives in training and marketing materials that conflict with the protocol.

69. For example, the Primex study protocol indicates "the expected duration of this clinical trial … is approximately 2 years but will be highly dependent on retrospective specimen collection and/or prospective subject enrollment." In practice, however, and on information and belief, DNA Stat and Primex intend the study to continue indefinitely so that it can facilitate their fraud on Medicare. DNA Stat trains the sales representatives to tell physicians the study was open-ended, so they need not worry about the payments stopping.

70. On information and belief, the intent of the study and the reason it is open-ended in duration is to increase test volume.

71. Similarly, on information and belief, in practice DNA Stat applies much broader "inclusion criteria" than the sanitized explanation in the Primex study protocol. The protocol describes the inclusion criteria as follows: "specimens from subjects who are on multiple medications of which at least 2 are affected by the pathways tested …." But DNA Stat contradicts this in its training and marketing documents, training sales representatives to promulgate broader criteria, such as for any patients on a single medication.

72. In this vein, the Defendants in practice disregard numerous procedures outlined in the Primex study protocol. The protocol indicates that it is provided to every investigator (*i.e.*, the physicians requesting the test panels), but on information and belief, DNA Stat, Primex, and RDI, in fact, do not provide the protocol to *any* physicians, even if they request it.

73. The protocol places numerous other requirements on the physicians that DNA Stat, Primex, and RDI did not actually implement, such as providing a "written report" at the

conclusion of the study, "assessing the clinical performance characteristics evaluated," record keeping, training, documenting test operators, and posting Institutional Review Board ("IRB") approval in the offices. Thus, the conspirator's blatant disregard for the procedural safeguards in the protocol demonstrates that the safeguards are merely window-dressing for the kickback scheme.

74. Next, the stated objective of the study is as follows: "if the physician makes any changes to the subject's medication regimen, then in 3 months he/she will assess the changes and report the findings; hence establishment of the clinical utility of our test." Besides the fact that a study without any defined end point facially lacks any scientific value for establishing "clinical utility," the protocol does not account for the fact that physicians have a financial incentive to make a change.

75. In addition to inconsistencies between the Primex study protocol and the conspirators' practices, DNA Stat's numerous false claims about the study further illustrate it is a sham and constitute independent grounds for liability. For example, DNA Stat claims that the study is the "only FDA-Approved clinical study in the U.S. for pharmacogenetics" and that it is "supervised by the FDA and … CMS, which is the Center for Medicare and Medicaid Services." In reality, according to the National Institute of Health database, there are hundreds of studies involving pharmacogenomics or pharmacogenetics. Additionally, the FDA and CMS do not typically "supervise" studies, so it is unclear what DNA Stat means by this claim. But, Defendants' overall intent appears to be to give the imprimatur of propriety and government approval of their kickback scheme.

2. Primex, DNA Stat, and RDI Provide Free Medical Technicians as Kickbacks to High-Performing Physicians

76. In addition to the kickbacks in the form of monetary payments for the so-called "study data," DNA Stat provides physicians with a free medical technician if they meet a quota of requested tests (150 tests/month). The purpose of the technicians is ostensibly to administer the tests (buccal swabs), but the real intent is to drive test volume and provide a kickback to the physicians in the form of free labor (and perhaps a job for a friend or relative).

77. On information and belief, a significant percentage of tests are ordered by physicians where DNA Stat has placed a free technician in the physician's office.

78. DNA Stat trains its sales representatives to ask physicians if they have a friend or relative that could be hired as the free technician. Thus, the free medical technician not only drives test volume, but the free labor and job for an "insider" provide an indirect inducement for the physician to order additional test panels.

3. Primex, DNA Stat, and RDI Procure Medically Unnecessary Tests

79. DNA Stat sales representatives are trained to instruct physicians to request the full panoply of nine test panels, regardless of whether they are needed for an individual patient. On information and belief, physicians that do not request all the panels do not receive their payments, and the sales reps are instructed that Primex will only perform all nine panels, regardless of the physicians' own analysis of medical necessity. As previously discussed, if a physician is properly considering medical necessity, the physician should determine what panels

would be appropriate for each individual patient based on the patient's medications, medical history, and other patient-specific factors.[12]

80. Defendants' training webinar, however, indicates that DNA Stat "packages" all panels in the test, and that DNA Stat "automatically" requests all nine panels. The trainer repeatedly inculcates the trainees with the message that anything but 9 panels is not an option.

81. On information and belief, the purpose of this practice is to increase the reimbursements from Medicare. If physicians requested something less than all nine panels, Medicare would not reimburse for the full $958, and it would reduce profits for the Defendants.

82. In trying to justify this approach, the DNA Stat trainer states that even if only a single pathway (*i.e.*, panel) is relevant for a patient's medication, the patient likely will be on more medications in the future. The net effect of this practice is that Medicare reimburses for panels that are not medically necessary.

83. When a physician enrolls in the "study," she is required to fill out a "Panel Request Form" that acknowledges the physician understands that she should only request panels that she believes are medically necessary. But, on information and belief, this self-serving form has no impact on the physicians in practice (and demonstrates fraudulent intent) because the sales representatives instruct the physicians that requesting all 9 panels is required to receive the kickback.

84. In addition to requiring 9 panels, DNA Stat trains its sales representatives to apply broader criteria for patient inclusion than Medicare allows. The clinical trial protocol and DNA Stat's own training state that the Medicare criteria for medical necessity (*i.e.*, the criteria for

[12] Social Security Act, § 1862(a)(1).

Medicare to reimburse for pharmacogenomic testing) is that a patient must be on 2 or more prolonged medications. But DNA Stat trains its sales representative to market the tests for "any patient on medications or being placed on medication." This practice also causes fraudulent test panels to be reimbursed by Medicare that are not medically necessary.

85. On information and belief, DNA Stat management, including CEO Mr. Edland and COO Sam Brooks, know about and promulgate the policy of using a lower standard for medical necessity than that approved by the Medicare program.

D. The Scheme Specifically Targets Medicare

86. Defendants specifically target physicians with heavy Medicare populations, such as geriatric physicians, internal medicine physicians, pain management physicians, and cardiologists. On information and belief, about 80% of DNA Stat's revenue derives from Medicare reimbursements. Unlike most private payors, Medicare covers 100% of the cost of the test panels, a fact DNA Stat sales representatives emphasize with physicians.

87. In fact, if physicians are concerned that private payors require copays, they are trained to suggest that the physician "test Medicare patients only." Medicare reimburses Primex for the tests, who, on information and belief, filters the money back to the other Defendants.

88. Additionally, DNA Stat representatives inform physicians that Primex will not vigorously follow up with patients to collect the patient's copay share for private insurance patients, thereby overstating how much is actually charged to private insurance patients. This practice creates potential liability under the FCA/or and other laws and regulations because Medicare providers like Primex are generally required to accurately report private insurance charges because it can affect how much Medicare will reimburse for the Medicare patient

tests.[13] Also, it is illegal for DNA Stat to use its failure to pursue non-Medicare bills as a way to induce physicians to request more tests for Medicare patients.

89. DNA Stat trains its sales representatives to inform physicians about this "light-handed billing practice." DNA Stat training indicates the whole business model has been designed so that it is sound financially if Primex never collects a single bit of the patient's share and that it is intended merely to give the appearance of compliance. The materials DNA Stat gives to patients similarly indicate DNA Stat has a "patient friendly billing policy." In addition to its potential illegality in its own right, this practice demonstrates that the conspirators' fraudulent scheme specifically targets Medicare dollars.

E. Relators David Choate and Don Pyburn Uncover the Fraud

90. Before working for DNA Stat, Relator David Choate worked since 1997 for Farmers Insurance, initially as an independent contractor and later for 10 years as a district manager. Mr. Choate previously worked with another Farmer's district manager Tim Martin, who, on information and belief, had left the insurance industry to enter the medical industry several years before.

91. Mr. Martin told Mr. Choate about a new business venture he was taking part in that appeared promising. Mr. Martin's company has a prime marketing contract with DNA Stat (along with other intermediaries at this level), and he contracted with a second level of independent contractors that were tasked with hiring sales representatives on behalf of DNA Stat.

92. On October 4, 2013, Mr. Choate contracted with Tim Martin's company Affiliated Consulting Group to hire and train sales representatives for DNA Stat. Mr. Choate has

[13] Center for Medicare & Medicaid Services, Clinical Laboratory Fee Schedule, available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/

since hired and facilitated the training of over 35 sales representatives that DNA Stat trained to commit fraudulent practices described in this disclosure, hiring more sales representatives for DNA Stat than any other intermediary (at the time of his resignation).

93. Relator Don Pyburn worked for 35 years in various industries including heavy industrial, chemical, petro-chemical, refining, oil and gas pipeline construction, and commercial real estate development, including being in corporate management and ownership of several companies..

94. Relators Choate and Pyburn met at a church-related retreat, and Mr. Choate introduced the idea to Mr. Pyburn of working part-time as a DNA Stat sales representative. Mr. Pyburn contracted with Mr. Choate's company Premier Medical Solutions on October 16, 2013.

95. Relators When Mr. Pyburn learned about the way DNA Stat was inducing physicians to order tests by participating in a clinical study and by providing free medical assistants, he became suspicious and started looking into the legality of these practices.

96. After Mr. Pyburn raised these issues with Mr. Choate, Mr. Choate quickly shared his concerns, and they resolved to seek confirmation that the practices were legal and ethical. Relators Pyburn and Choate's concerns were only intensified by discussing the practices with a physician Mr. Pyburn had signed up to participate in the sham "clinical study."

97. The Relators discussed their concerns with the legality of DNA Stat, Primex, and RDI's practices with Tim Martin at a meeting in Lufkin Texas on October 31, 13. At that time, they requested a meeting with DNA Stat management in Dallas to discuss several concerns.

98. The Relators met with DNA Stat Management on November 14, 2013. The Relators asked for a legal opinion that they could give to physicians regarding the legality of the

payments to physicians. In response, DNA Stat COO Sam Brooks became defensive and evasive. He indicated that although DNA Stat did not have a legal opinion justifying its actions, he would check with Primex for a legal opinion. Mr. Brooks mentioned that he travelled almost weekly to Primex and would obtain it when he next travelled to California if he could not request it on a call before then.

99. At the Dallas meeting the Relators also noted the discrepancy in the inclusion criteria between the marketing materials and the training. In particular, the marketing materials reflected the Medicare standard of medical necessity of 2 prolonged medications, but representatives were trained that a single medication was sufficient to qualify for a test. Mr. Brooks agreed this should be changed (but, on information and belief, it was never changed prior to Mr. Choate and Mr. Pyburn's resignations). At the meeting Mr. Martin and Mr. Brooks also mentioned the benefits of giving physicians free medical technicians as a way for DNA Stat to increase test volume.

100. After the meeting in Dallas, the Relators followed up with Mr. Martin several times to request the legal opinion confirming legality. Mr. Martin initially provided several excuses regarding Mr. Brooks' travel schedule and other issues, but several weeks passed with no results. After the second or third request, Mr. Martin's tone changed and he became very defensive.

101. When it became clear DNA Stat would not confirm the legality of these practices, the Relators resigned. Mr. Pyburn gave Mr. Choate his notice of his resignation on December 1, 2013, and Mr. Choate sent his resignation letter to Mr. Martin on December 13, 2013.

VII. COUNT 1 (VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3729(A)(1)(A))

102. Relators incorporates herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

103. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and upon information and belief, are still presenting or causing to be presented, to the United States of America false or fraudulent claims for payment or approval, in violation of 31 U.S.C. § 3729(a)(1)(A).

104. In particular, Defendants knowingly presented or caused to be presented, and upon information and believe, are continuing to present or causing to be presented, to the United States of America false or fraudulent claims for payment or approval based on conduct in violation of the Anti-kickback Statute and/or the Stark Law. Defendants caused and are continuing to cause physicians and other medical professionals to order pharmacogenomic tests reimbursed by Medicare by providing kickbacks and illegal inducements to the physicians and medical professionals. Defendants provided and are continuing to provide the kickbacks and illegal inducements in the form of direct payments based on the volume of tests ordered and in exchange for participation in a sham "clinical study," and in the form of free medical technicians tied to volume, in violation of 31 U.S.C. § 3729(a)(1)(A).

105. Defendants also knowingly presented or caused to be presented, and upon information and believe, are continuing to present or causing to be presented, to the United States of America false or fraudulent claims for payment or approval of pharmacogenomic tests that were not medically necessary. Tests were not medically necessary because Defendants

required and are continuing to require physicians to request every possible test panel, regardless of the physician's consideration of individual medical necessity, in violation of 31 U.S.C. § 3729(a)(1)(A). Also, tests were not medically necessary because Defendants were inducing physicians and other medical professionals to apply a lower standard for medical necessity than that required by the Medicare program, in violation of 31 U.S.C. § 3729(a)(1)(A).

106. Defendants also knowingly presented or caused to be presented, and upon information and believe, are continuing to present or causing to be presented, to the United States of America false or fraudulent claims for payment or approval of pharmacogenomic tests based on Defendant Primex's false certification of compliance with laws and regulations. On information and belief, as an Independent Diagnostic Testing Facility ("IDTF") enrolled to provide services reimbursed by Medicare, Primex is required to fill out a certificate of compliance with the Anti-kickback Statute, the Stark Law, and other laws and regulations. By committing acts in violation of the Anti-kickback Statute, the Stark Law, the False Claims Act, state false claims acts and similar statutes, and/or other laws and regulations, Primex's certificates of compliance became and continue to be false or fraudulent, in violation of 31 U.S.C. § 3729(a)(1)(A).

107. Defendants knowingly presented or caused to be presented, and upon information and believe, are continuing to present or causing to be presented, to the United States of America false or fraudulent claims for payment or approval based on false statements made to physicians and other medical professionals regarding the existence of the sham "clinical study" Defendants used as an inducement for physicians and other medical professionals to order pharmacogenomic tests. In addition to false statements regarding the existence, objectives, and purposes of the so-

called study, Defendants made and upon information and belief are continuing to make false statements regarding features of the so-called study, such as, for example, that it is the "only FDA-Approved clinical study in the U.S. for pharmacogenetics" and that it is "supervised by the FDA and … CMS," and related statements regarding government approval of or supervision over the so-called study, in violation of 31 U.S.C. § 3729(a)(1)(A).

108. As a result of the conduct set forth in this cause of action, the Government suffers and continues to suffer harm as a result of paying or reimbursing for tests which, had the Government known such tests were being ordered as a result of the conduct, the Government would not otherwise have paid for/or reimbursed.

109. By reason of the Defendants' acts in violation of the False Claims Act, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

VIII. COUNT 2 (VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3729(A)(1)(B))

110. Relators incorporate herein by reference the preceding paragraphs of this Complaint as though fully set forth herein.

111. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and upon information and belief, are still making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim, in violation of 31 U.S.C. § 3729(a)(1)(B).

112. In particular, Defendants knowingly made, used, or caused to be made or used, and upon information and belief, are still making, using, or causing to be made or used, false or

fraudulent claims for payment or approval based on conduct in violation of the Anti-kickback Statute and/or the Stark Law. Defendants caused and are continuing to cause physicians and other medical professionals to order pharmacogenomic tests reimbursed by Medicare by providing kickbacks and illegal inducements to the physicians and medical professionals. Defendants provided and are continuing to provide the kickbacks and illegal inducements in the form of direct payments based on the volume of tests ordered and in exchange for participation in a sham "clinical study," and in the form of free medical technicians tied to volume, in violation of 31 U.S.C. § 3729(a)(1)(B).

113. Defendants also knowingly made, used, or caused to be made or used, and upon information and belief, are still making, using, or causing to be made or used, false or fraudulent claims for payment or approval of pharmacogenomic tests that were not medically necessary. Tests were not medically necessary because Defendants required and are continuing to require physicians to request every possible test panel, regardless of the physician's consideration of individual medical necessity, in violation of 31 U.S.C. § 3729(a)(1)(B). Also, tests were not medically necessary because Defendants were inducing physicians and other medical professionals to apply a lower standard for medical necessity than that required by the Medicare program, in violation of 31 U.S.C. § 3729(a)(1)(B).

114. Defendants also knowingly made, used, or caused to be made or used, and upon information and belief, are still making, using, or causing to be made or used, false or fraudulent claims for payment or approval of pharmacogenomic tests based on Defendant Primex's false certification of compliance with laws and regulations. On information and belief, as an Independent Diagnostic Testing Facility ("IDTF") enrolled to provide services reimbursed by

Medicare, Primex is required to fill out a certificate of compliance with the Anti-kickback Statute, the Stark Law, and other laws and regulations. By committing acts in violation of the Anti-kickback Statute, the Stark Law, the False Claims Act, state false claims acts or similar statutes, and/or other laws and regulations, Primex's certificates of compliance became and continue to be false or fraudulent, in violation of 31 U.S.C. § 3729(a)(1)(B).

115. Defendants also knowingly made, used, or caused to be made or used, and upon information and belief, are still making, using, or causing to be made or used, false or fraudulent claims for payment or approval of pharmacogenomic tests based on false or fraudulent statements made to physicians and other medical professionals regarding the existence of the sham "clinical study" Defendants used as an inducement for physicians and other medical professionals to order pharmacogenomic tests. In addition to false or fraudulent statements regarding the existence, objectives, and purposes of the so-called study, Defendants made and upon information and belief continue to make false or fraudulent statements regarding features of the so-called study, such as, for example, that it is the "only FDA-Approved clinical study in the U.S. for pharmacogenetics" and that it is "supervised by the FDA and … CMS," and related statements regarding government approval of or supervision over the so-called study.

116. As a result of the conduct set forth in this cause of action, the Government suffers and continues to suffer harm as a result of paying or reimbursing for tests which, had the Government known such tests were being ordered as a result of the conduct, the Government would not otherwise have paid for/or reimbursed.

117. By reason of the Defendants' acts in violation of the False Claims Act, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

IX. COUNT 3 (VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3729(A)(1)(C))

118. Relators incorporate herein by reference the preceding paragraphs of this Complaint as thought fully set forth herein.

119. As detailed above, Defendants knowingly conspired, and upon information and belief, continue to conspire with each other and with health care professionals and "independent contractors," such as for example DNA Stat sales representatives and other sales intermediaries, and DNA Stat pharmacists, identified and described herein, to commit acts in violation of 31 U.S.C., §§ 3729(a)(1)(A) & (B). Defendants and these health care professionals and "independent contractors" committed overt acts in furtherance of the conspiracy as described above.

120. As a result of the conduct set forth in this cause of action, the Government suffers and continues to suffer harm as a result of paying or reimbursing for tests which, had the Government known such tests were being ordered as a result of the conduct, the Government would not otherwise have paid for/or reimbursed.

121. By reason of the Defendants' acts in violation of the False Claim Act, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

X. PRAYER FOR RELIEF

WHEREFORE, Relators respectfully requests this Court to enter judgment against Defendants, as follows:

a. That Defendants be ordered to cease and desist from submitting or causing to be submitted any more false or fraudulent claims, or making, using, or causing to be made or used, false records or statements material to a false or fraudulent claim, or further violating 31 U.S.C. § 3729 *et seq.*, the Anti-kickback Statute, and/or the Stark Law;

b. That judgment be entered in Relators' favor and against Defendants in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per claim as provided by 31 U.S.C. § 3729(a), to the extent such multiplied penalties shall fairly compensate the Unites States of America for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

c. That Relators be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d), including reasonable attorneys' fees and litigation costs;

d. That judgment be granted for Relators and against Defendants for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relators in the prosecution of this suit; and

e. That Relators be granted such other and further relief as the Court deems just and proper.

XI. DEMAND FOR JURY TRIAL

Relators, on behalf of themselves and the United States, demand a jury trial on all issues so triable.

Dated: May 7, 2014

Respectfully submitted,

FISH & RICHARDSON P.C.

By: _____

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SEALED

3-14CV-1691B

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

The United States of America ex. rels., David Choate and Don Pyburn

DEFENDANTS

DNA Stat, Primex Clinical Laboratories, Inc., Research and Development Institute Incorporated, and Mitch Edland

(b) County of Residence of First Listed Plaintiff Dallas
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Dallas
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

RECEIVED
MAY - 7 2014
CLERK U.S. DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

(c) Attorney's (Firm Name, Address, and Telephone Number)
(see attachment)

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☒ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**):
31 USC 3729

Brief description of cause:
False Claims Act-Qui Tam Lawsuit (Medicare Fraud)

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $ to be determined

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
05/07/2014

SIGNATURE OF ATTORNEY OF RECORD
Walker

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

ATTACHMENT TO CIVIL COVER SHEET

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